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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,841	08/02/2001	Alain Rambach	1567P368	8188

7590 02/02/2005
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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,841

Applicant(s)

RAMBACH ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The application should be reviewed for errors. As noted in the first Office action, error occurs, for example, in the spelling of “galatosidase” in claim 6. Error occurs also in the recitation “bacteria contains”, since bacteria are plural.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/05 has been entered.

Claims 1-3, 5-9 and 25-27 are being considered on the merits.

The amendment filed 12/16/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: At least at pages 1, 4, 6, 7, 9, 10, 12-15, 17-19, the replacement of abbreviations with chemical names, including the replacement of abbreviations such as “X-ACGLMN” (or X-acglmn), “MAG- α -Gal” and “MAL-phos” with “X-GlcNac” or “5-bromo-4-chloro-indolyl-N-acetyl-b-D-glucosaminide”; “MAGENTA-Gal or “5-bromo-6-chloro-3-indolyl-b-D-galactopyranoside” and “MAG phos” or 5-bromo-6-chloro-3-indolyl-phosphate; respectively.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's allegations that “X-ACGLMN” (or X-acglmn) was “improperly recited in the application” and should properly be “X-GlcNac” or “5-bromo-4-chloro-indolyl-N-acetyl-b-D-glucosaminide”; that MAG- α -Gal “corresponds to” “MAGENTA-Gal and that the full name is “5-bromo-6-chloro-3-indolyl-b-D-galactopyranoside” or that MAL-phos is properly “MAG phos” which is 5-bromo-6-chloro-3-indolyl-phosphate have not been substantiated with appropriate evidence. There is nothing on the record to indicate how the alleged errors occurred

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or why they were not corrected earlier. It is noted that upon signing the oath or declaration, Applicant acknowledges having reviewed and understood the specification and claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-9 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the now inserted full chemical names in claim 1. There is no clear nexus between the abbreviations used and the chemical names provided in the instant specification.

No clear basis or support is found in the present specification for a culture medium as recited in claim 25 comprising

- 1) at least one metal complex
- 2) a substrate containing an indoxyl chemical derivative and further comprising
- 3) a medium containing bacteria having been cultured under anaerobic conditions
- 4) at least one substrate containing an indoxyl chemical derivative resulting in an insoluble colored compound
- 5) at least one oxidizing metal complex, wherein at least one oxidizing metal complex is ammoniacal iron citrate, and wherein the bacteria contains one of an appearance of a colored precipitate around the colonies, a color of the colonies, and both an appearance of a colored precipitate around the colonies and a color of the colonies.

Therefore, this material raises the issues of new matter and should be deleted.

Response to Arguments

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Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's allegations that "X-ACGLMN" (or X-acglmn) was "improperly recited in the application" and should properly be "X-GlcNac" or "5-bromo-4-chloro-indolyl-N-acetyl-b-D-glucosaminide"; that MAG- α -Gal "corresponds to" "MAGENTA-Gal and that the full name is "5-bromo-6-chloro-3-indolyl-b-D-galactopyranoside" or that MAL-phos is properly "MAG phos" which is 5-bromo-6-chloro-3-indolyl-phosphate have not been substantiated with appropriate evidence. There is nothing on the record to indicate how the alleged errors occurred or why they were not corrected earlier. It is noted that upon signing the oath or declaration, Applicant acknowledges having reviewed and understood the specification and claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-9 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and inconsistent in the use of "indoxyl" and "indolyl". Claim 1 is also vague and indefinite in the recitation of "at least one metal complex **which allows** the oxidative polymerization ... to result in an insoluble colored compound". Similarly, claim 27 is confusing in the recitation "comprising an enzyme allowing the release". It is unclear under which circumstances the complex or the enzyme will or will not "allow" the respective reactions to occur.

Claim 2 is vague and indefinite in the recitation "preferably 0.6 mg/ml". The phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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Claim 6 is vague and indefinite in the recitation of “aerobic anaerobic bacteria”. It is unclear what is intended. Applicant argues that this is a term of art. However, no evidence in this regard was provided.

Claims 25 and 26 are vague and indefinite in that the ingredients of the composition intended cannot be readily determined. The culture medium as recited in claim 25 appears to comprise at least one metal complex and a substrate containing an indoxyl chemical derivative and a second medium containing bacteria having been cultured under anaerobic conditions, a further at least one substrate containing an indoxyl chemical derivative resulting in an insoluble colored compound and at least one further oxidizing metal complex, wherein at least one oxidizing metal complex is ammoniacal iron citrate, and wherein the bacteria contains one of an appearance of a colored precipitate around the colonies, a color of the colonies, and both an appearance of a colored precipitate around the colonies and a color of the colonies.

Claim 25 is vague and indefinite in that it is unclear whether “and containing at least one substrate” under a) pertains to the bacteria or to the medium.

In claims 25 and 27 the nature of the indoxyl chemical derivative is not disclosed with any particularity and the type of “derivative” intended is unclear. In claim 1, specific “indolyl” derivatives” are recited. Also “a color of the colonies” fails to indicate whether this is the native color of the colonies or different therefrom.

While product by process claims are proper, the claims 25-27 as written depend on product claim and process steps are included under “further comprising”, including a process of culturing bacteria. In addition, the phrase “wherein the bacteria contains one of an appearance of a colored precipitate around the colonies, a color of the colonies, and both an appearance of a colored precipitate around the colonies and a color of the colonies” is not understood. It is unclear how bacteria are to “contain” “an appearance of a colored precipitate around the colonies” in a composition claim. Similarly, it is unclear how the bacteria are to “contain” “a color of the colonies” in a composition claim. Applicant is reminded that the claims are drawn to a bacterial culture medium and not to a process of using the culture medium to detect bacteria.

Also the extensive use of “b” rather than “ β ” in the specification and claims is queried. These terms do not appear to be interchangeable. See, also, claim 6.

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Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Regarding “aerobic anaerobic”, the Google search is not informative, since the terms appear to be used as “(aerobic) Anaerobic”, “aerobic/anaerobic”, “aerobic-anaerobic” or “aerobic, anaerobic”. Only one cite contains the terms “facultatively aerobic anaerobic bacteria”, but no definition of the terminology is provided. Therefore, the rejection is deemed proper and it is maintained.

With regard to claims 25-26, as noted in the last Office action, the intended limitations are not readily ascertainable, and applicant's arguments fail to persuade otherwise. Contrary to applicant's arguments, claims 25 and 26 contain the recitation of “having been cultured” or “is cultured, respectively, which are process steps.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller *et al.*.

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Miller discloses a medium comprising 5-bromo-4-chloro-3-indolyl- β -D-galactopyranoside (X-gal) and ferric ammonium citrate. (See, e.g., Example 1 and col. 4).

Regarding the intended use, it is noted that *Salmonella* may be grown under anaerobic conditions.

Claims 1-3, 5-9 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller *et al.* taken with Chevalier *et al.* and Difco Manual.

The Miller *et al.* reference is discussed above.

The reference differs from the claimed invention in the use of magnesium sulfate and/or an antibiotic in the medium. However, Chevalier discloses a similar medium for the detection of bacteria, such as Lactobacilli MRS medium which contains magnesium sulfate in combination with chromogenic substrates for the detection of α -galactosidase (See, e.g., Chevalier, page 77, Difco Manual, pages 246-247). Moreover, Chevalier *et al.* disclose that the use of antibiotics in selective media is a well known technique in the art (See, e.g., page 76, paragraph 1).

In addition, the use of cysteinated Columbia medium is old and well known in the art, as adequately demonstrated by Difco Manual (See, e.g., pages 125-126). Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the medium of Miller *et al.* by replacing sodium thiosulfate with magnesium sulfate in the medium or by using cysteinated Columbia medium in conjunction with chromogenic substrates with or without antibiotics for the expected benefit of providing a medium capable of selectively detecting deleterious bacteria.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that Chevalier and Difco are improperly combined because different microorganisms are intended to be cultured and because different additives are supplied to the medium. Applicant's argument that the "references teach entirely distinct inventive purposes and neither teach or suggest usefulness outside the scope of the claimed invention" is puzzling.

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In any event, there is nothing in DIFCO to suggest that the cysteinated Columbia medium must be used in the alleged context of blood agar. The reference merely suggests that it may be used to make blood agar. Applicant's attention is directed to the box at page 126, for example, which does not mandate the inclusion of blood in the composition. Therefore, one of ordinary skill in this art would have been motivated to use cysteinated Columbia medium instead of MRS agar, for example in the medium of Chevalier, since at least *Streptococcus* are cultured both in Difco and in Chevalier. Therefore, applicant's arguments in this regard are without merit.

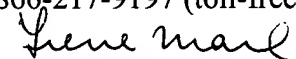
Therefore the rejections are deemed proper and are adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx
Primary Examiner
Art Unit 1651